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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| DEAK, LESLIE R | |

| ART UNIT | PAPER NUMBER |
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| 3761 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/812,380 | KHAN ET AL. | |
| | Examiner | Art Unit | |
| | Leslie R. Deak | 3761 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 December 2006, 16 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Arguments*

1. The affidavits filed on 16 May 2007 under 37 CFR 1.131 is sufficient to overcome the Smego reference.

2. Applicant's arguments and affidavits have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of US 6,102,884 to Squitieri. Since the claims were in condition for Final Rejection upon entry of applicants 11 December 2006 amendment, Examiner presents a second Final Rejection based on the claims as presented 11 December 2006 and currently pending.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 7, 10, 13, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,102,884 to Squitieri.

In the specification and figures, Squitieri discloses the device as claimed by applicant. With regard to claim 1, Squitieri discloses an arteriovenous shunt system comprising an arterial graft 53 with a lead end 19 anastomosed to an artery and terminal end connected to reservoir or cuff 50. The system further comprises a venous

outflow catheter 65 with an outflow end that is capable of being inserted through a vein into the right atrium of the heart (see FIGS 6-9) and an inflow end that is connected to reservoir or cuff 50 (see column 5, lines 19-60). The system further comprises a reservoir 50, or, in an alternate embodiment, tubing 64/69, that corresponds to applicant's cuff wherein the reservoir or tubing is capable of directing passage of blood from the arterial catheter to the venous catheter, and the reservoir or tubing inlet is in communication with the terminal end of the arterial graft and ther eservoir or tubing outlet is in communication with the inlet end of the venous catheter (see FIGS 6-9, column 5, lines 19-60).

With regard to applicant's claim limitation drawn to the venous outflow catheter "configured for insertion through a vein into the right atrium of the heart," applicant fails to set forth any structural limitations that distinguish the claimed catheter from that disclosed by Squitieri. It is the position of the examiner that the venous outflow catheter disclosed by Squitieri is, without any structural modifications, capable of being deployed in a patient's right atrium, meeting the limitations of applicant's claim.

With regard to claims 2, 3, and 7, Squitieri discloses that in one embodiment, tubing or cuff 69 is made of PTFE (polytetrafluoroethylene), a biocompatible, flexible material (see FIG 8, column 5, lines 55-60).

With regard to claim 10, Squitieri discloses that in one embodiment, the venous catheter may comprise silicone tubing (see column 5, lines 25-29).

With regard to claim 13, Squitieri discloses that the arteriovenous graft system may be connected to a hemodialysis machine (not shown), meeting the limitations of the claim (see column 4, lines 60-64).

With regard to claim 17, Squitieri discloses that the graft may be surgically inserted (see column 7, lines 24-45), connected to a hemodialysis machine (which, by definition, purifies blood), collect blood through the arterial catheter, send the blood through a dialysis machine, and collect blood from the dialysis machine and return it to the patient via the venous catheter (see column 4, lines 50-64).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 4, 5, 8, 9, 12, 14, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri.

In the specification and figures, Squitieri discloses the device and method substantially as claimed by applicant with the exception of the specific catheter sizes claimed by applicant. Squitieri discloses that the shunt may be manufactured in a variety of different linear lengths and interior and exterior diameter sizes (see column 3, line 60 to column 4, line 15). It has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device

and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP 2144.04(IV)(A). It appears that the device and method disclosed by Squitieri would perform in the same manner as claimed by applicant. Therefore, the sizes claimed by applicant are held by the examiner to be an obvious variation of the device and method disclosed by Squitieri.

7. Claims 6, 11, 15, 16, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,591,226 to Trerotola et al.

In the specification and figures, Squitieri discloses the device and method substantially as claimed by applicant with the exception of the particular arteries and veins that are used to connect to the arteriovenous system. Squitieri is silent as to the particular vessels used, but it is well-known in the art of arteriovenous grafts that one may select any given vessel based on the suitability for its purpose. Trerotola discloses a stent-graft that may be deployed between many vessels within a patient, and discloses a graft between a brachial artery and an axillary vein (see FIG 9A and accompanying text). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to connect the arteriovenous graft system disclosed by Squitieri to the brachial artery and axillary vein as disclosed by Trerotola in order to create blood flow between the selected vessels, as demonstrated by Trerotola.

***Conclusion***

8. Applicant's 11 December 2006 amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
23 May 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER